

REMARKS

Claims 52-77 have been allowed as indicated in the Notice of Allowance mailed September 15, 2004. Applicants have not submitted or otherwise authorized payment of the issue fee. Through this paper, Applicants have amended claims 52 and 61 to correct typographical errors. Claim 71 has been amended to recite the appropriate dependency. New dependent claim 78 has been added. Support for these amendments and the new claim can be found throughout the application including the claims as originally filed. Applicants believe these amendments introduce no new matter.

The undersigned attorney has received the Examiner's amendment with appreciation and respectfully requests that the amendments contained herein be entered.

Applicants also respectfully request that the Examiner return to the undersigned an initialed copy of Form PTO-1449 submitted January 29, 2004, as it has not yet been received. For the Examiner's convenience, a copy of the submission of January 29, 2004, along with a copy of the date-stamped mailroom postcard indicating the submission was received by the Patent Office on February 2, 2004, are attached as Exhibit A.

If any additional fees are required by this submission, the Commissioner is hereby authorized to charge Attorney's Deposit Account No. 20-0531.

Respectfully submitted,



Date: September 30, 2004
Reg. No. (Limited Recognition
Under CFR 10.9(b))
Tel. No. (617) 248-7808
Fax No. (617) 248-7100

Duan Wu
Attorney for Applicants
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125 High Street
Boston, MA 02110

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EV334240723US

COPY

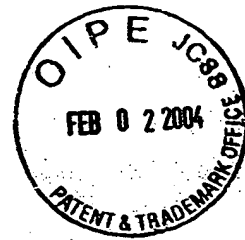


INL-053 (4643/95)

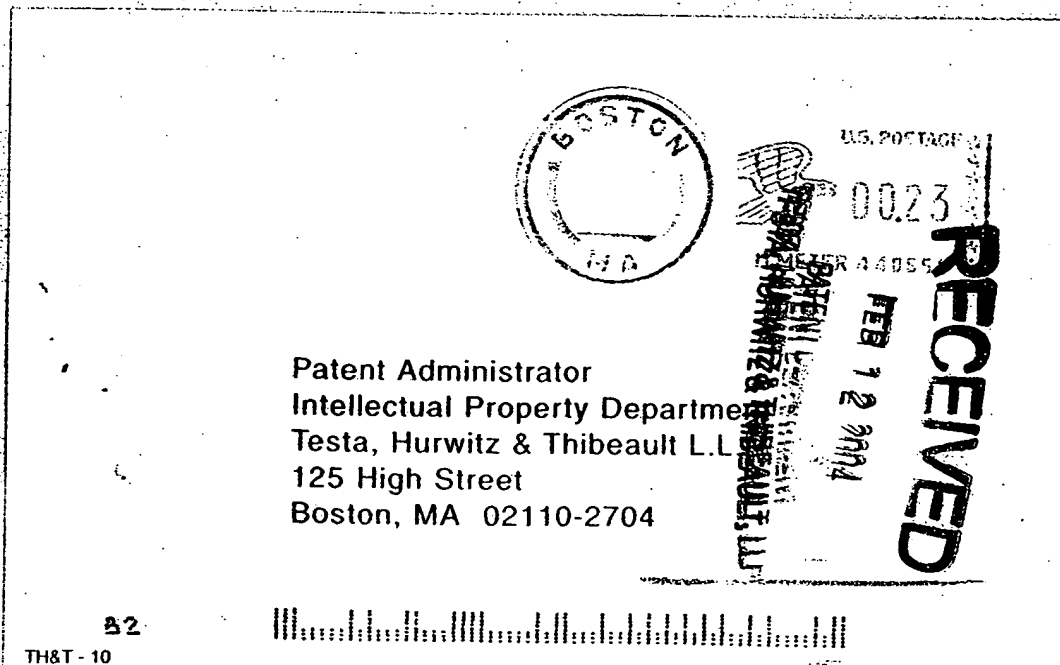
The "Received" stamp of the Patent Office imprinted hereon acknowledges the filing of:

Certificate of First Class Mailing (1 pg.); Transmittal Form (1 pg.); Fifth Supplemental Information Disclosure Statement (2 pgs.); Supplemental PTO-1449 Form (1 pg.); Copies of Cited References A45 and C165; and a return-receipt postcard.

Applicant: Dai et al.
Serial No.: 10/029,406
Atty: RPMoore/DMSSteel
Date: January 29, 2004
3014209



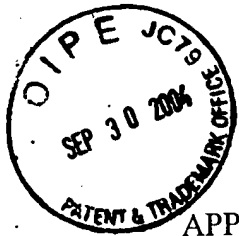
BEST AVAILABLE COPY



PATENT

Attorney Docket No. INL-053
(4643/95)

COPY



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Dai et al.
SERIAL NO.: 10/029,406 GROUP NO.: 1651
FILING DATE: December 19, 2001 EXAMINER: Not yet assigned
TITLE: PROTEIN S FUNCTIONAL ASSAY

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 29th day of January, 2004.


Brenda T. Kowalczyk

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith is/are:

- Transmittal Form (1 pg.);
- Fifth Supplemental Information Disclosure Statement (2 pgs.);
- Certificate of First Class Mailing (1 pg.);
- Supplemental PTO-1449 Form (1 pg.);
- Copies of Cited References (A45 & C165); and a
- Return-Receipt Postcard.

TRANSMITTAL
FORM



Application Serial Number	10/029,406
Filing Date	December 19, 2003
First Named Inventor	Dai
Group Art Unit	1651
Examiner Name	Not Yet Assigned
Attorney Docket No.	INL-053
Patent No.	Not applicable
Issue Date	Not applicable

COPY

ENCLOSURES (check all that apply)

- | | | |
|---|--|---|
| <input type="checkbox"/> Fee Transmittal Form
<input type="checkbox"/> Check Attached
<input type="checkbox"/> Copy of Fee Transmittal Form
<input type="checkbox"/> Amendment/Response
<input type="checkbox"/> Preliminary
<input type="checkbox"/> After Final
<input type="checkbox"/> Affidavits/declaration(s)
<input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____]
<input type="checkbox"/> Petition for Extension of Time
<input checked="" type="checkbox"/> Fifth Supplemental Information Disclosure Statement
<input checked="" type="checkbox"/> Form PTO-1449
<input checked="" type="checkbox"/> Copies of IDS Citations
<input type="checkbox"/> Certified Copy of Priority Document(s)
<input type="checkbox"/> Sequence Listing submission
<input type="checkbox"/> Paper Copy/CD
<input type="checkbox"/> Computer Readable Copy
<input type="checkbox"/> Statement verifying identity of above | <input type="checkbox"/> Copy of Notice to File Missing Parts of Application (PTO-1553)
<input type="checkbox"/> Formal Drawing(s)
<input type="checkbox"/> Request For Continued Examination (RCE) Transmittal
<input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)
<input type="checkbox"/> Terminal Disclaimer
<input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application
<input type="checkbox"/> Small Entity Statement
<input type="checkbox"/> CD(s) for large table or computer program
<input type="checkbox"/> Amendment After Allowance
<input type="checkbox"/> Request for Certificate of Correction
<input type="checkbox"/> Certificate of Correction (in duplicate) | <input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences
<input type="checkbox"/> Appeal Brief (in triplicate)
<input type="checkbox"/> Status Inquiry
<input checked="" type="checkbox"/> Return Receipt Postcard
<input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8
<input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8
<input type="checkbox"/> Additional Enclosure(s) (please identify below) |
|---|--|---|

COPY

CORRESPONDENCE ADDRESS

Direct all correspondence to: Patent Administrator
Testa, Hurwitz & Thibault, LLP
High Street Tower
125 High Street
Boston, MA 02110
Tel. No.: (617) 248-7000
Fax No.: (617) 248-7100

SIGNATURE BLOCK

Respectfully submitted,

Date: January 29, 2004
Reg. No. 43,153
Tel. No.: (617) 310-8168
Fax No.: (617) 248-7100

Diana M. Steel
Attorney for Applicants
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PATENT
Attorney Docket No. INL-053
(4643/95)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Dai et al.
SERIAL NO.: 10/029,406 GROUP NO.: 1651
FILING DATE: December 19, 2001 EXAMINER: Not yet assigned
TITLE: PROTEIN S FUNCTIONAL ASSAY

COPY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**

☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

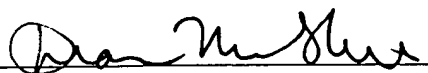
- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

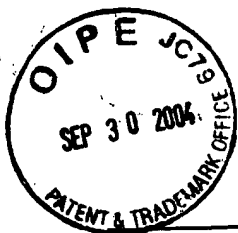
Respectfully submitted,

Date: January 29, 2004
Reg. No. 43,153

Tel. No.: (617) 310-8168
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3014195


Diana M. Steel
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125 High Street
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Page 1 of 1

FORM PTO - 1449

FIFTH SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: INL-053

APPLICANT(S): Dai et al.

SERIAL NO.: 10/029,406

FILING DATE: December 19, 2001 GROUP: 1651

COPY

U.S. PATENT DOCUMENTS

EXAM INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A45	5,147,805	09/15/92	Preda <i>et al.</i>	436	86	

FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)

OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C165	Notification of Transmittal of International Preliminary Examination Report for International Patent Application No. PCT/US01/50338, dated December 19, 2000, 6 pages.
EXAMINER		DATE CONSIDERED

3014198

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EV334240723US

PATENT COOPERATION TREATY

RECEIVED
2004
C165

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
DIANA M. STEEL
TESTA, HURWITZ & THIBEAULT, LLP
HIGH STREET TOWER - 125 HIGH STREET
BOSTON, MA 02110

COPY
PATENT COOPERATION TREATY
TESTA, HURWITZ & THIBEAULT, LLP

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year) **12 JAN 2004**

Applicant's or agent's file reference

INL-053 PC

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US01/50338

19 December 2001 (19.12.2001)

19 December 2000 (19.12.2000)

Applicant

INSTRUMENTATION LABORATORY COMPANY

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703)305-3230

Form PCT/IPEA/416 (July 1992)

Authorized officer

Sandra Saucier

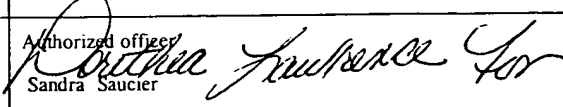
Telephone No. (703)308-0196

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

COPY

Applicant's or agent's file reference INL-053 PC	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US01/50338	International filing date (day/month/year) 19 December 2001 (19.12.2001)	Priority date (day/month/year) 19 December 2000 (19.12.2000)
International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/56 and US Cl.: 435/13		
Applicant INSTRUMENTATION LABORATORY COMPANY		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u> </u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input checked="" type="checkbox"/> Certain defects in the international application</p> <p>VIII <input checked="" type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 18 July 2002 (18.07.2002)	Date of completion of this report 11 December 2003 (11.12.2003)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer  Sandra Saucier Telephone No. (703)308-0196	

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-20 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☒ the claims:
pages 21-25, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☒ the drawings:
pages 1, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>5-13, 15-21, 26</u>	YES
	Claims <u>1-4, 14, 22-25</u>	NO
Inventive Step (IS)	Claims <u>5-13, 15-21, 26</u>	YES
	Claims <u>1-4, 14, 22-25</u>	NO
Industrial Applicability (IA)	Claims <u>1-26</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-4, 14, 22-25 lack novelty under PCT Article 33(2) as being anticipated by US 5,147,805.

US 5,147,805 discloses a method for measuring protein S activity comprising:

Mixing a sample of test plasma with protein S-deficient plasma, bovine thromboplastin, phospholipid, calcium ion, and activator of protein C which forms activated protein C in the mixture, measuring the clotting time, comparing the measurement to a standard curve (col. 3, l. 20) generating by testing plasma samples having a range of protein S activities. Kits of reagents are also taught.

Claims 5-13, 15-21, 26 meet the criteria set out in PCT Article 33(2)-(3), because the prior art cited in the search report does not teach or fairly suggest the claimed invention.

Claims 1-26 meet the criteria set out in PCT Article 33(4), and thus provide industrial applicability because the subject matter claimed can be made or used in industry.

NEW CITATIONS

US 5,147,805 A (PREDA et al.) 15 September 1992, see entire article.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US01/50338

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 25 and 26 are misnumbered.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claim 1 states that "calcium" is added to the mixture; however, it is calcium ION which is added. The claims are replete with abbreviations and parenthetical insertions which should be removed.